REMARKS

Claims 1-3, 6, 7, 13-18 and 20 were canceled. Claims 4, 5, 8-12, 19 and 21-50 are pending. Claims 19 and 21-33 were withdrawn. Claims 4, 5, 8-12, and 34-50 have been rejected.

I. Claim Rejections.

In the Office Action mailed October 27, 2009, the Examiner rejected the claims on the following grounds: 1) Claims 5, 34-50 were rejected under 35 U.S.C. §112, first paragraph "because the specification, while being enabling for benzoyl peroxide (BPO) particles of less than 50 microns as claimed by claim 4, does not reasonably provide enablement for any other active ingredient having particle size between 10-150 microns as claimed by claim 5, up to 300 microns as claimed by claim 34 or less than 50 microns as claimed by claim 35"; and 2) Claims 4, 5, 8-12, 34-50 are rejected under 35 U.S.C. §112, second paragraph "as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." Applicant respectfully traverses these rejections and requests reconsideration for the reasons stated below.

I. 35 U.S.C. §112, first paragraph.

The Examiner argues that "the specification, while being enabling for benzoyl peroxide (BPO) particles of less than 50 microns as claimed by claim 4, does not reasonably provide enablement for any other active ingredient having particle size between 10-150 microns as claimed by claim 5, up to 300 microns as claimed by claim 34 or less than 50 microns as claimed by claim 35. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims." *Office Action*, page 3. The Examiner asserts that after consideration of the *In re Wands* factors, "it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation." *Id.*

Applicant respectfully traverses the Examiner's arguments. The MPEP states:

> The enablement requirement refers to the requirement of 35 U.S.C. 112, first paragraph that the specification describe how to make and how to use the

> invention. The invention that one skilled in the art must be enabled to make and use is that defined by the claim(s) of the particular application or patent. The purpose of the requirement that the specification describe the invention in such terms that one skilled in the art can make and use the claimed invention is to ensure that the invention is communicated to the interested public in a meaningful way. The information contained in the disclosure of an application must be sufficient to inform those skilled in the relevant art how to both make and use the claimed invention.

MPEP §2164.

Given the disclosures of dermatologically active ingredients and particle size ranges in Applicant's specification, one of ordinary skill in the art would be enabled to make and practice the claimed compositions with any insoluble dermatologically active ingredient in the full range of particle sizes described in the claims. A declaration by Dr. Eugene H. Gans (attached as Exhibit 1 to Request for Reconsideration dated April 7, 2010), an inventor of the present application and one of ordinary skill in the art, demonstrates that the disclosures in the specification enable one of ordinary skill in the art to make and use the claimed invention.

A. Disclosures Concerning Insoluble Dermatologically Active Ingredients.

Insoluble, dermatologically active ingredients described in Applicant's specification are known in the art. As Dr. Gans states, "Persons skilled in the art of dermatologic formulations are highly familiar with insoluble, dermatologically active ingredients. These ingredients have been widely used for decades (in some cases, almost a century). The selection, preparation and use of these ingredients is part of the essential repertoire of any person skilled in the art of dermatologic formulations." Gans Declaration, at ¶ 7. Applicant's specification provides "[s]everal examples of insoluble dermatologically active ingredients" including at paragraph 16, "zinc oxide, iron EDTA, magnesium peroxide, minocycline, hydrocortisone, BPO and sulfur." Gans Declaration at ¶¶ 8, 9. "More such ingredients are described in standard dermatological references." Gans Declaration, ¶ 8. *See* Exhibit A to Declaration of Eugene H. Gans, Ph.D. (references to various insoluble dermatologically active ingredients). For example, "In *Harry's Cosmeticology*, colloidal kaolin (pp. 107-108; 116-117), zinc oxide (pp. 107; 331), talcum powder (p. 249), colloidal calamine (p. 331), are disclosed as insoluble dermatologically active ingredients." Gans Declaration, at ¶ 10. BPO is but one example of an insoluble dermatologically active ingredient.

As Dr. Gans states, "The physical and chemical properties of insoluble dermatologically active ingredients are well known to one skilled in this art. Their stability, their reactivity with other ingredients, their biochemical effects, and a host of other properties are well known or readily available to persons skilled in this art. Thus, it is well within the knowledge and skill of one skilled in this art to make dermatologic formulations with insoluble dermatologic ingredients." Gans Declaration, at ¶ 12. One of ordinary skill in the art would readily practice the claimed invention using any insoluble dermatologically active ingredient without undue experimentation, given that persons skilled in the art are highly familiar with insoluble dermatologically active ingredients, and their properties. As Dr. Gans points out, "This base of well-established and widely shared knowledge, taken together with the disclosures found in the application, would make it a routine matter for one skilled in the dermatologic art to practice the claimed invention using any insoluble dermatologically active ingredient." Gans Declaration, at ¶ 13 (emphasis added).

B. Disclosures Concerning Particle Size.

Just as persons skilled in the art are highly familiar with insoluble, dermatologically active ingredients, "[p]ersons skilled in the art of dermatologic formulations are highly familiar with using particles of various sizes in topical formulations." Gans Declaration, at ¶ 14. As Dr. Gans states, "The techniques for obtaining and controlling particle size in this context have been known for decades to persons skilled in this art. These techniques include milling and grinding, as well as a variety of sieving and washing techniques." Gans Declaration, at ¶ 15. Using these very well know techniques, a person of ordinary skill in the art is able to obtain particle sizes for any insoluble dermatologically active ingredient. "The broad array of techniques that are within the repertoire of dermatologic formulations enables them to produce insoluble dermatologically active ingredients having almost any particle size that might be desired. Persons skilled in the art would simply select whichever of the well-known techniques for obtaining particle size was best suited to result in obtaining the desired size for the particular insoluble dermatologically active ingredient.." Gans Declaration, at ¶ 15.

Not only are various particle sizes able to be easily obtained by one of ordinary skill in the art given these known techniques, but "The claims of the application specify certain particle

size. Claim 34 calls for the particles to be up to about 300 microns. Claim 35 calls for the particles to be less than about 50 microns. Claim 5 calls for the particles to be in the range of from about 10 to about 150 microns. All of these particle sizes are easily obtained using the above mentioned techniques." Gans Declaration, at ¶ 17.

As shown by the Gans declaration, it is clear that persons skilled in the art are highly familiar with insoluble, dermatologically active ingredients and obtaining various particle sizes for such active ingredients using well-known techniques. As stated by Dr. Gans, "Persons working in this field have long been familiar with insoluble particle dermatology active ingredients, and with techniques for controlling the size of these particles. However, the inventors and I were the first to discover that the regulation of particle size and viscosity, as called for in the claims of this application, would enable an emulsion containing these ingredients to be reliably applied to a pad or cloth, and yet obtain excellent release of the insoluble particulate active ingredient to the skin." Gans Declaration, at ¶ 19. The knowledge of one of ordinary skill in the art regarding insoluble, dermatologically active ingredients, as well as particle sizes, combined with the disclosures in Applicant's specification of dermatologically active ingredients and particle size ranges is "sufficient to inform those skilled in the relevant art how to both make and use the claimed invention." MPEP §2164.

II. 35 USC §112, second paragraph.

A. "Substantially Uniformly" Is Definite.

The Examiner argues that "substantially uniformly" is a term "not defined by the claim, the specification does not provide a standard of ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention." *Office Action*, page 6. However, the Examiner's conclusory statements are mistaken as "substantially uniformly" is a proper and definite term used in claim language.

The Federal Circuit has endorsed the use of "substantially" in its decisions. According to the Federal Circuit, the use of the term "substantially" is proper and definite when used in claim language. In discussing the term "substantially equal," the court states that "[s]uch usages, when serving to reasonably to describe the claimed subject matter to those of skill in the field of the invention, and to distinguish the claimed subject matter from the prior art, have been accepted in

patent examination and upheld by the courts." *Andrew Corp. v. Gabriel Electronics, Inc.*, 847 F.2d 819, 821 (Fed. Cir. 1988); *see also* MPEP §2173.05(b). In fact, in a case addressing the use of "substantially uniformly" (practically identical to Applicant's "substantially uniform"), the Federal Circuit in *Ecolab, Inc. v. Envirochem, Inc.* found that the "language 'substantially uniform' expressly modifies the term 'alkaline detergent'" and is acceptable claim drafting practice. 264 F.3d 1358, 1366 (Fed. Cir. 2001). As in *Ecolab*, "the use of the term 'substantially' to modify the term 'uniform' does not render this phrase so unclear such that there is no means by which to ascertain the claim scope." *Id.* at 1367.

In fact, patents have been issued from the United States Patent Office ("USPTO") in which "substantially" was used in the claims, including in the specific phrase "substantially uniformly." For example, in U.S. Patent No. 7,452,356 (attached as Exhibit 2 to Request for Reconsideration dated April 7, 2010), the USPTO allowed the following claims:

> 1. A dermatologic treatment apparatus, comprising a light source providing pulses of light having an output fluence of 4-100J/cm^2 at a target area of a patient and having sufficient fluence to cause hair removal at the target area; and optical apparatus for distributing light from the light source ***substantially uniformly*** across an input of a diffuser wherein the diffuser diffuses the light sufficiently to cause the apparatus to be eye-safe during treatment while maintaining sufficient fluence to cause hair removal at the target area of a patient.
>
> 14. The apparatus of claim 10 wherein the optical apparatus distributes the light ***substantially uniformly*** across the outlet.
>
> 25. The apparatus of claim 24 wherein the optical apparatus comprises a mixer for distributing light ***substantially uniformly*** at the outlet.
>
> 28. A dermatologic hair-regrowth-inhibiting apparatus, comprising a light source comprising one or more laser diodes configured to produce pulses of light in a hair-regrowth-inhibiting procedure wherein the pulses are of sufficient fluence to inhibit hair-regrowth in a target area of a patient; a mixer, having an outlet, for ***substantially uniformly*** distributing light from the light source across the outlet; a diffuser, disposed to receive light from the outlet, for diffusing the light sufficiently that the pulses of light emitted from an output of the diffuser are eye-safe at all distances while remaining of sufficient fluence to inhibit hair-regrowth in the target area of the patient; and wherein the majority of the fluence of the light pulses is within a spectral band of 500 nm to 1100 nm, the pulses have a pulse duration between 10 milliseconds and 1 second, and the fluence at the target area is between 4 J/cm^2 and 100 J/cm^2.

> 31. A dermatologic apparatus for removing hair comprising a divergent light source comprising a plurality of laser diode bars each comprising a plurality of laser diode emitters and configured to produce pulses of light substantially within the spectral band of 500 nm to 1100 nm to effect hair removal in a target area of a patient, the pulses of light having a fluence at the target area between 4 J/cm^2 and 100 J/cm^2 and each pulse having a pulse duration between 10 milliseconds and 1 second, a mixer, having an outlet, for ***substantially uniformly*** distributing the light pulses across the outlet, and a bulk transmissive diffuser, disposed to receive light from the outlet, for diffusing the light sufficiently that the pulses of light emitted from an output of the diffuser are eye-safe during a hair removal treatment.
> (***emphasis added***)

Applicant has only cited one of the numerous issued patents that contain the word "substantially," and specifically the phrase "substantially uniformly" in the claims. Clearly, the USPTO itself has recognized the propriety of the term "substantially" in patent claims, and has issued patents using the term.

Therefore, given the Federal Circuit's express endorsement of the use of "substantially" and particularly "substantially uniform," the use of "substantially uniformly" does not render the claims indefinite.

B. "Less Than About 50 Microns" and "Up To About 300 Microns" Are Definite.

The Examiner argues that "[t]he expression 'less than about 50 microns' as claimed by claims 4 and 35 is indefinite because the term 'less than' requires sizes below 50 microns only. To the contrary, the term 'about' permits sizes above 50 microns." The Examiner further argues "[t]he expression 'up to about 300 microns' as claimed by claim 34 is indefinite because the term 'up to' requires sizes below 300 microns only. To the contrary, the term 'about' permits sizes above 300 microns." *Office Action*, page 6.

The terms "less than about" and "up to about" are understood by one of ordinary skill in the art, as evidenced in U.S. Patent Nos. 7,648,695 (Claims 1 and 3 - "less than about"); 7,477,938 (Claim 10 - "less than about"); 7,452,547 (Claims 1, 2, 11, 13 and 14 – "less than about"); 7,628,997 (Claims 1 and 6 - "up to about"); 7,521,404 (Claims 1, 15, 19, and 20 - "up to

about"); 7,300,669 (Claim 4 - "up to about"), attached as Exhibits 3, 4, 5, 6, 7, and 8 to Request for Reconsideration dated April 7, 2010.

Applicant notes that "less than" and "up to" are upper limitations on the particle sizes and one of ordinary skill in the art would understand their meaning. Further, the term "about" has been held to be definite. *See* MPEP § 2173.05(b). *See also Conopco, Inc. v. May Department Stores Co.*, 784 F. Supp. 648, 670, 24 USPQ2d at 1735-36 (E.D. Mo. 1992) , *rev'd in part, aff'd in part, & remanded with instructions*, 46 F.3d 1556, 32 USPQ2d 1225 (Fed. Cir. 1994), *cert. denied*, 514 U.S. 1078 (1995) (stating "[u]se of the word 'about' in a claim is appropriate where the claim contains a range of components with no absolute boundaries"). Moreover, reference to the claims of United States Patent No. 7,628,997 (attached hereto as Exhibit 6 to Request for Reconsideration dated April 7, 2010), demonstrates that use of the term "about" is acceptable when identifying particle sizes. Claims 1 and 6 of U.S. Patent No. 7,628,997 states "In a method of preserving a perishable cosmetic preparation, the improvement comprising adding from 0.1 to 25 percent by weight of bioactive glass particles with ***particles sizes (d_{50}) up to about*** 10 μm to said perishable cosmetic preparation" and "In a perishable cosmetic preparation, the improvement comprising including from 0.1 to 25 percent by weight of bioactive glass particles with ***particles sizes (d_{50}) up to about 10 μm*** in said perishable cosmetic preparation." (emphasis added)

Applicant has only cited a few of the numerous issued patents which contain the terms "less than about" and "up to about" in the claims. Such common usage of these terms indicates that these terms are not ambiguous; rather, these terms are clearly understood by those in the art. Accordingly, this rejection should be withdrawn.

CONCLUSION

In view of the foregoing remarks, Applicant respectfully requests consideration and allowance of the pending claims. Finally, Applicant respectfully submits a request for a personal interview with the Examiner, in order to further resolve any outstanding issues.

Authorization of Deposit Account

The Commissioner is hereby authorized to charge any fees which may be required during the entire pendency of this application, or credit any overpayment, to Deposit Account No. 18-0586. This authorization also hereby includes a request for any extensions of time of the appropriate length required upon the filing of any reply during the entire pendency of this application.

Respectfully submitted,
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